



**DEPARTMENT OF DEFENSE**

**BILLING CODE 5001-06**

**Office of the Secretary**

**32 CFR Part 199**

**Docket ID: DoD-2013-HA-0085**

**RIN: 0720-AB60**

**Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/**

**TRICARE: Pilot Program for Refills of Maintenance Medications for TRICARE For Life Beneficiaries through the TRICARE Mail Order Program**

**AGENCY:** Office of the Secretary, Department of Defense (DoD).

**ACTION:** Interim final rule.

**SUMMARY:** This interim final rule implements Section 716 of the National Defense Authorization Act for Fiscal Year 2013 which establishes a five year pilot program that would generally require TRICARE for Life beneficiaries to obtain all refill prescriptions for covered maintenance medications from the TRICARE mail order program or military treatment facility pharmacies. Covered maintenance medications are those that involve recurring prescriptions for chronic conditions, but do not include medications to treat acute conditions. Beneficiaries may opt out of the pilot program after one year of participation. This rule includes procedures to assist beneficiaries in transferring covered prescriptions to the mail order pharmacy program. This regulation is being issued as an interim final rule in order to comply with the express statutory intent that the program begin early in calendar year 2013. Public comments, however, are invited and will be considered for possible revisions to this rule for the second year of the program.

**DATES:** This rule is effective [insert 65 days after date of publication in the Federal Register].

Written comments received at the address indicated below by [insert 60 days after date of publication in the Federal Register] will be considered and addressed in the final rule.

**ADDRESSES:** You may submit comments, identified by docket number and/or RIN number and title, by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>.

Follow the instructions for submitting comments.

Mail: Federal Docket Management System Office, 4800 Mark Center Drive, Suite 02G09, Alexandria, VA 22350.

*Instructions:* All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this Federal Register document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

**FOR FURTHER INFORMATION CONTACT:** Rear Admiral Thomas McGinnis, Chief, Pharmacy Operations Directorate, TRICARE Management Activity, telephone 703-681-2890.

## **SUPPLEMENTARY INFORMATION:**

### **A. EXECUTIVE SUMMARY**

#### **1. Purpose.**

This interim final rule implements section 716 of the National Defense Authorization Act for Fiscal Year 2013, which establishes a five year pilot program requiring TRICARE for Life beneficiaries to obtain all prescription refills for select maintenance medications from the TRICARE mail order program or military treatment facilities.

The legal authority for this rule is section 716 of the National Defense Authorization Act for Fiscal Year 2013. Subsection (d) of that law requires the issuance of this rule.

2. Summary of the major provisions of the interim final rule.

TRICARE for Life beneficiaries are required to obtain all prescription refills for select maintenance medications from the TRICARE mail order program (where beneficiary copayments are much lower than in retail pharmacies) or military treatment facilities (where there are no copayments). TRICARE for Life beneficiaries are those TRICARE beneficiaries enrolled in the Medicare wraparound coverage option of the TRICARE program. Covered maintenance medications are those prescribed for chronic, long-term conditions that are taken on a regular, recurring basis, but do not include medications to treat acute conditions. TRICARE will follow best commercial practices, including that beneficiaries will be notified of the new rules and mechanisms to allow them to receive adequate medication during their transition to mail for their refills. The statute and rule authorize a waiver of the mail order requirement based on patient needs and other appropriate circumstances. Beneficiaries may opt out of the program after one year of participation. The program will expire December 31, 2017, unless extended by Congress.

3. Costs and benefits.

The effect of the statutory requirement, implemented by this rule, is to shift a volume of prescriptions from retail pharmacies to the mail order pharmacy program. This will produce savings to the Department of approximately \$120 million during the initial year of the demonstration and savings to beneficiaries of approximately \$28 million in reduced copayments during the initial year of the demonstration. Savings to both Department and the beneficiaries are

expected to increase approximately four percent per year during the remainder of the demonstration.

## **B. BACKGROUND.**

In Fiscal Year 2012, 70 million prescriptions were filled for TRICARE beneficiaries through the TRICARE retail pharmacy benefit at a net cost of \$3.8 billion to the government. Of those prescriptions, 33 million or 47% were filled for TRICARE for Life beneficiaries at a cost of \$2.2 billion to the government. On average, the government pays 17% less for maintenance medication prescriptions filled in the mail order program than through the retail program. Not all prescriptions filled through the retail program are maintenance/chronic medications. Those that are not are excluded from the program. However, there is potential for significant savings to the government by shifting a portion of the TRICARE for Life prescription refills to the mail order program. In addition, there will be significant savings to the TRICARE for Life beneficiaries who will receive up to a 90 day refill at no charge for generics in the mail order program compared to a \$5 copay for only up to a 30 day refill in retail. The savings is even greater for brand-name prescriptions: \$13 for up to 90 days in mail versus \$17 for up to 30 days in retail, meaning that for a 90-day supply the copayment comparison is \$13 in mail to \$51 in retail. The non-formulary copayment comparison is \$43 for up to 90 days in mail compared to \$44 for only up to 30 days in retail.

## **C. PROVISIONS OF THE INTERIM FINAL RULE.**

The interim final rule adds a new paragraph (r) to 32 C.F.R. section 199.21. The new paragraph (r) establishes rules for the new program of refills of maintenance medications for TRICARE for Life beneficiaries through the mail order pharmacy program. Paragraph (r)(1) requires that for covered maintenance medications, TRICARE for Life beneficiaries are

generally required to obtain their prescription refills through the national mail order pharmacy program or through military treatment facility pharmacies. TRICARE for Life beneficiaries are those enrolled in the Medicare wraparound coverage option of the TRICARE program.

Paragraph (r)(2) provides that the Director, TMA will establish, maintain, and periodically revise and update a list of covered maintenance medications, which will be accessible through the TRICARE Pharmacy Program Web Site and by telephone through the TRICARE Pharmacy Program Service Center. Each medication included on the list will be a medication prescribed for a chronic, long-term condition that is taken on a regular, recurring basis. It will be clinically appropriate and cost effective to dispense the medication from the mail order pharmacy. It will be available for an initial filling of a 30-day or less supply through retail pharmacies, and will be generally available at military treatment facility pharmacies for initial fill and refills. It will be available for refill through the national mail-order pharmacy.

Paragraph (r)(3) provides that a refill is a subsequent filling of an original prescription under the same prescription number or other authorization as the original prescription, or a new original prescription issued at or near the end date of an earlier prescription for the same medication for the same patient.

Paragraph (r)(4) provides that a waiver of the general requirement to obtain maintenance medication prescription refills from the mail order pharmacy or military treatment facility pharmacy will be granted in several circumstances. There is a blanket waiver for prescription medications that are for acute care needs. There is also a blanket waiver for prescriptions covered by other health insurance. There is a case-by-case waiver to permit prescription maintenance medication refills at a retail pharmacy when necessary due to personal need or hardship, emergency, or other special circumstance, for example, for nursing home residents.

This waiver is obtained through an administrative override request to the TRICARE pharmacy benefits manager under procedures established by the Director, TMA.

Paragraph (r)(5) establishes procedures for the effective operation of the program. The Department will implement the program by utilizing best commercial practices to the extent practicable. An effective communication plan that includes efforts to educate beneficiaries in order to optimize participation and satisfaction will be implemented. Beneficiaries with active prescriptions for a medication on the maintenance medication list will be notified that their medication is covered under the program. Beneficiaries will be advised that they may receive up to two 30 day fills at retail while they transition their prescription to the mail order program. The beneficiary will be contacted after each of these two fills reminding the beneficiary that the prescription must be transferred to mail. Requests for a third fill at retail will be blocked and the beneficiary advised to call the pharmacy benefits manager (PBM) for assistance. The PBM will provide a toll free number to assist beneficiaries in transferring their prescriptions from retail to the mail order program. With the beneficiary's permission, the PBM will contact the physician or other health care provider who prescribed the medication to assist in transferring the prescription to the mail order program. In any case in which a beneficiary is required to obtain a maintenance medication prescription refill from the national mail-order pharmacy program and attempts instead to refill such medications at a retail pharmacy, the PBM will also maintain the toll free number to assist the beneficiary. This assistance may include information on how to request a waiver or in taking any other appropriate action to meet the beneficiary's needs and to implement the program. The PBM will ensure that a pharmacist is available at all times through the toll-free telephone number to answer beneficiary questions or provide other appropriate assistance.

Paragraph (r)(6) provides that any beneficiary who has been covered by the program for a period of at least one year may opt out of continuing to participate in the program. For this purpose, the starting date for this one-year period is the first date after the effective date of this regulation on which the beneficiary had a maintenance medication prescription filled through the mail order pharmacy program. The beneficiary may exercise his or her right to opt out of the program by contacting the PBM. Following an opt out, the beneficiary may obtain prescriptions from a retail pharmacy, subject to the normal limitations and procedures under the TRICARE Pharmacy Benefits Program. Beneficiaries may also, if they wish, obtain refills from military treatment facility pharmacies and the mail order pharmacy program.

Paragraph (r)(7) provides that the program and its requirements will expire December 31, 2017, unless Congress enacts a statutory extension of the program. If this happens, the program will automatically continue, with any adjustments or modifications required by law.

#### **D. REGULATORY PROCEDURES.**

##### ***Executive Order 12866, “Regulatory Planning and Review” and Executive Order 13563, “Improving Regulation and Regulatory Review”***

Executive Orders (EOs) 12866 and 13563 require that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined primarily as one that would result in an effect of \$100 million or more in any one year. The DoD has examined the economic and policy implications of this interim rule and has concluded that it is an economically significant regulatory action under the Executive Orders. The pilot program will produce savings to the Department of approximately \$120 million during the initial year of the demonstration and savings to beneficiaries of approximately \$28 million in reduced copayments during the initial year of the demonstration. Savings to both Department and the

beneficiaries are expected to increase approximately four percent per year during the remainder of the demonstration.

***Congressional Review Act, 5 U.S.C. 801, et seq.***

Under the Congressional Review Act, a major rule may not take effect until at least 60 days after submission to Congress of a report regarding the rule. A major rule is one that would have an annual effect on the economy of \$100 million or more or have certain other impacts.

This interim rule is a major rule under the Congressional Review Act.

***Sec. 202, Pub. L. 104-4, “Unfunded Mandates Reform Act”***

This rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of \$100 million or more (adjusted for inflation) in any one year.

***Public Law 96-354, “Regulatory Flexibility Act” (5 U.S.C. 601)***

The Regulatory Flexibility Act (RFA) requires that each Federal agency prepare and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This interim rule does not have a significant impact on a substantial number of small entities.

***Public Law 96-511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35)***

This interim rule contains no new information collection requirements subject to the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3511).

***Executive Order 13132, “Federalism”***

This interim rule does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on the States; the relationship between



the National Government and the States; or the distribution of power and responsibilities among the various levels of Government.

***Public Comments Invited***

This rule is being issued as an interim final rule based on the express Congressional intent in the Conference Report accompanying the final version of the bill, that the provision enacted was to “require the Secretary to conduct the 5-year mail-order pilot program for TRICARE for Life beneficiaries.” Because of the statutory sunset date of December 31, 2017, it is the clear Congressional intent that the program begin as soon as possible in calendar year 2013. DoD invites public comments on all provisions of the rule. They will be considered for possible revisions to the program for the second and subsequent years of operation.

Accordingly, 32 CFR part 199 is proposed to be amended as follows:

**PART 199--[AMENDED]**

1. The authority citation for part 199 continues to read as follows:

**Authority:** 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.21 is amended by revising the section heading and adding a new paragraph (r) to read as follows:

**§ 199.21. TRICARE Pharmacy Benefits Program.**

\* \* \* \* \*

(r) Refills of maintenance medications for TRICARE for Life beneficiaries through the mail order pharmacy program--(1) In general. Consistent with section 716 of the National Defense Authorization Act for Fiscal Year 2013, this paragraph requires that for covered maintenance medications, TRICARE for Life beneficiaries are generally required to obtain their prescription through the national mail-order pharmacy program or through military treatment

facility pharmacies. For purposes of this paragraph, TRICARE for Life beneficiaries are those enrolled in the Medicare wraparound coverage option of the TRICARE program made available to the beneficiary under section 1086(d) of title 10, United States Code.

(2) Medications covered. The Director, TMA will establish, maintain, and periodically revise and update a list of covered maintenance medications subject to the requirement of paragraph (r)(1) of this section. The current list will be accessible through the TRICARE Pharmacy Program Internet Web Site and by telephone through the TRICARE Pharmacy Program Service Center. Each medication included on the list will meet the following requirements:

(i) It will be a medication prescribed for a chronic, long-term condition that is taken on a regular, recurring basis.

(ii) It will be clinically appropriate to dispense the medication from the mail order pharmacy.

(iii) It will be cost effective to dispense the medication from the mail order pharmacy.

(iv) It will be available for an initial filling of a 30-day or less supply through retail pharmacies.

(v) It will be generally available at military treatment facility pharmacies for initial fill and refills.

(vi) It will be available for refill through the national mail-order pharmacy program.

(3) Refills covered. For purposes of the program under paragraph (r)(1), a refill is:

(i) A subsequent filling of an original prescription under the same prescription number or other authorization as the original prescription; or

(ii) A new original prescription issued at or near the end date of an earlier prescription for the same medication for the same patient.

(4) Waiver of requirement. A waiver of the general requirement to obtain maintenance medication prescription refills from the mail order pharmacy or military treatment facility pharmacy will be granted in the following circumstances:

(i) There is a blanket waiver for prescription medications that are for acute care needs.

(ii) There is a blanket waiver for prescriptions covered by other health insurance.

(iii) There is a case-by-case waiver to permit prescription maintenance medication refills at a retail pharmacy when necessary due to personal need or hardship, emergency, or other special circumstance. This waiver is obtained through an administrative override request to the TRICARE pharmacy benefits manager under procedures established by the Director, TMA.

(5) Procedures. Under the program established by paragraph (r)(1) of this section, the Director, TMA will establish procedures for the effective operation of the program. Among these procedures are the following:

(i) The Department will implement the program by utilizing best commercial practices to the extent practicable.

(ii) An effective communication plan that includes efforts to educate beneficiaries in order to optimize participation and satisfaction will be implemented.

(iii) Beneficiaries with active retail prescriptions for a medication on the maintenance medication list will be notified that their medication is covered under the program. Beneficiaries will be advised that they may receive up to two 30 day fills at retail while they transition their prescription to the mail order program. The beneficiary will be contacted after each of these two fills reminding the beneficiary that the prescription must be transferred to mail.

(iv) Requests for a third fill at retail will be blocked and the beneficiary advised to call the pharmacy benefits manager (PBM) for assistance.

(v) The PBM will provide a toll free number to assist beneficiaries in transferring their prescriptions from retail to the mail order program. With the beneficiary's permission, the PBM will contact the physician or other health care provider who prescribed the medication to assist in transferring the prescription to the mail order program.

(vi) In any case in which a beneficiary required under paragraph (r) of this section to obtain a maintenance medication prescription refill from national mail order pharmacy program and attempts instead to refill such medications at a retail pharmacy, the PBM will also maintain the toll free number to assist the beneficiary. This assistance may include information on how to request a waiver, consistent with paragraph (r)(4)(iii) of this section, or in taking any other appropriate action to meet the beneficiary's needs and to implement the program.

(vii) The PBM will ensure that a pharmacist is available at all times through the toll-free telephone number to answer beneficiary questions or provide other appropriate assistance.

(6) Nonparticipation through opt-out from program. Any beneficiary who has been covered by the program under paragraph (r)(1) of this section for a period of at least one year may opt out of continuing to participate in the program.

(i) For this purpose, the starting date for this one-year period is the first date after the effective date of paragraph (r)(1) of this section on which the beneficiary had a maintenance medication prescription filled through the mail order pharmacy program.

(ii) The beneficiary may exercise his or her right to opt out of the program by contacting the PBM.

(iii) Following an opt out, the beneficiary may obtain prescriptions from a retail pharmacy, subject to limitations under the TRICARE Pharmacy Benefits Program other than those under paragraph (r) of this section. These beneficiaries may also, if they wish, obtain refills from military treatment facility pharmacies and the mail order pharmacy program.

(7) Expiration of program. The program and requirements established under paragraph (r)(1) of this section will expire December 31, 2017, unless Congress enacts a statutory extension of the program. If this happens, the program will automatically continue, with any adjustments or modifications required by law.

Dated: December 5, 2013.

Aaron Siegel,  
Alternate OSD Federal Register Liaison Officer,  
Department of Defense.

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